OPINION RELATIVE TO MEDICINAL PRODUCTS

methotrexate

NORDIMET 25 mg/mL,

solution for injection in a pre-filled pen

New indication

Adopted by the Transparency Committee on 6 July 2022

SUMMARY

The legally binding text is the original French opinion version

- **Crohn's disease**
- **Sectors: Retail and hospital**

Key points

Favourable opinion for reimbursement in induction of remission in moderate steroid-dependent Crohn's disease in adult patients refractory or intolerant to thiopurines, in combination with corticosteroids and for maintenance of remission, as monotherapy, in patients who have responded to methotrexate.

What therapeutic improvement?

No clinical added value in the management of Crohn's disease.

Role in the care pathway?

In Crohn's disease, NORDIMET 25 mg/mL solution for injection in a pre-filled pen is a second-line treatment in corticosteroid-dependent adult patients refractory or intolerant to thiopurines; in moderate forms, the prescription of a TNF inhibitor may also be envisaged.

Committee's conclusions

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

In the treatment of Crohn's disease:

- Crohn's disease is a chronic inflammatory bowel disease. It progresses by flare-ups interspersed with remissions. It is a debilitating condition which can lead to a marked deterioration in quality of life.
- NORDIMET (methotrexate) is a symptomatic treatment.
- The efficacy/adverse effects ratio of subcutaneous methotrexate in the treatment of moderate forms of Crohn's disease, alone or in combination with corticosteroids, in **adults refractory or intolerant to thiopurines,** is moderate.
- There are alternatives for the management of patients refractory or intolerant to thiopurines (see clinically relevant comparators paragraph).
- NORDIMET (methotrexate) is a second-line treatment, in corticosteroid-dependent adults refractory or intolerant to thiopurines; the prescription of a TNF inhibitor may also be envisaged in moderate forms. The use of NORDIMET (methotrexate) in patients not refractory or intolerant to thiopurines is not recommended.

➔ Public health benefit

In the absence of new data, like its methotrexate-based comparators, NORDIMET (methotrexate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NORDIMET (methotrexate) is moderate in induction of remission in moderate steroid-dependent Crohn's disease in **adult patients refractory or intolerant to thiopurines**, in combination with corticosteroids and for maintenance of remission, as monotherapy, in patients who have responded to methotrexate.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in induction of remission in moderate steroid-dependent Crohn's disease in **adult patients refractory or intolerant to thiopurines**, in combination with corticosteroids and for maintenance of remission, as monotherapy, in patients who have responded to methotrexate, and at the MA dosages.

As regards patients who are non-refractory or tolerant to thiopurines, the clinical benefit is deemed to be insufficient to justify its public funding cover in view of the available alternatives.

Recommended reimbursement rate: 30%

Clinical Added Value

The Transparency Committee considers that NORDIMET 25 mg/mL solution for injection in a pre-filled pen (methotrexate) provides no clinical added value (CAV V) in the care pathway in adult patients with Crohn's disease compared to the other proprietary medicinal products containing methotrexate.